Jaguar Health Exploring Possibility of Conditional Marketing Authorization for Proposed Inflammatory Diarrhea Indication for Crofelemer, Initially in 'Long-Hauler' COVID-19 Recovery Patients in Europe

January 11, 2021

New COVID-19 strain estimated to have tripled number of infections in England during November 2020 lockdown

Investor webcast scheduled for Thursday, January 14 at 11:30 A.M. Eastern Time. Webcast registration link appears below

SAN FRANCISCO, CA / ACCESSWIRE / January 11, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") provided updates today regarding the Company's plans to explore the possibility of obtaining conditional marketing authorization in Europe to support development and commercialization of crofelemer, the Company's novel proprietary drug, for the proposed indication of prophylaxis and/or symptomatic relief of inflammatory diarrhea, initially to be studied in a "long-hauler" COVID-19 recovery patient population in Europe (the "COVID-related indication"). As part of the Company's investigation into the feasibility of the conditional marketing authorization pathway, which provides a fast-track clinical review process during public health emergencies, the Company plans to request meetings with the European Medicines Agency (EMA), Swissmedic, and the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom. The EMA, in particular, has established regulatory approval schemes for COVID-19-related treatments.

The head of emergencies at the World Health Organization stated on October 5, 2020 that the agency's "best estimates" indicate that roughly 1 in 10 people worldwide may have been infected by COVID-19 - more than 20 times the number of confirmed cases. According to the *New York Times*, the new, more contagious strain of COVID-19 has now been detected in 45 countries. Imperial College London estimates that the new strain tripled its number of infections in England during the November 2020 lockdown.

"The virus is moving with urgency, and so are we at Jaguar and Napo Pharmaceuticals, Inc. ("Napo"), Jaguar's wholly owned, U.S.-based subsidiary. I'm pleased that our internal team has prioritized this potential new indication for crofelemer. We are engaging a European regulatory firm that has experience with this conditional approval pathway in Europe," stated Lisa Conte, Jaguar's founder, president, and CEO. "With the appearance of more transmissible mutated strains of COVID-19, the potential population of post-COVID-19 recovery patients suffering from gastrointestinal distress associated with long-hauler syndrome may expand significantly. It's estimated that as high as one-third[1] of COVID-19-infected patients develop chronic or chronic episodic long-hauler syndrome - a constellation of post-viral infection symptoms. According to a November 1, 2020 *Wall Street Journal* article, the majority of the more than 300 long-COVID patients being seen at New York City's Mount Sinai Health System Center for Post-Covid Care appeared to have developed a dysautonomia-like condition, and about 40% to 50% of these patients also reported symptoms such as gastrointestinal issues, headaches and shortness of breath[2]. Based on these figures, the long-hauler population experiencing gastrointestinal distress could potentially range between 20 to 70 million people just in Europe.

The potential COVID-related indication for crofelemer is the subject of the proposed exclusive license from Napo to Napo EU, a subsidiary being established by the Company in Italy. As previously announced, Napo EU is the proposed target of a special purpose acquisition company (SPAC).

"The Company participated in a 'test the waters' road show in December which contemplated a proposed SPAC merger with a to-be-formed subsidiary of the Company, Napo EU, as the potential target. The timeline to establish Napo EU in Italy is being impacted by pandemic-necessitated administrative and government office closures. The roadshow included approximately 150 European institutional investors in four countries/six cities. The Company was encouraged by the apparent positive indications of interest expressed with this opportunity. We also believe our plans to pursue conditional marketing authorization in Europe for the COVID-related indication may add additional value to the potential indication, which is the subject of a proposed license to Napo EU. Subsequent to our roadshow, the Company received unsolicited investor interest for direct investment related to this initiative on what we believe are competitive terms. The Company continues to evaluate multiple financing pathways in order to optimize value for our shareholders and provide sufficient funding for the COVID-related indication in addition to the Company's full pipeline of indications. We expect to select our desired financing pathway no later than the end of this quarter."

"Our intention is to focus clinical exploration for the proposed COVID-related indication for crofelemer in Europe, where single-payer healthcare systems are interested in preventative measures to diagnose and treat symptoms early that can potentially reduce the burden of chronic illness later," Conte said.

"The timeline for potential approval will be discussed with the EMA in accordance with the conditional marketing authorization process," Conte added. To learn more about this process, click **here**.

During the January 14th investor webcast, Conte will provide updates on the status of the proposed COVID-related indication for crofelemer, as well as

Mytesi® (crofelemer) - Napo's commercialized antidiarrheal drug FDA-approved in the U.S. for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy - and the Company's full pipeline of potential crofelemer follow-on indications, including cancer therapy-related diarrhea, for which crofelemer is in a pivotal Phase 3 clinical trial in the U.S. In addition, Napo is supporting two investigator-initiated clinical studies in IBS/functional diarrhea in the U.S., and plans on studying congenital diarrheal disorders and short bowel syndrome, which are rare disease indications, using a novel formulation. Conte will also provide updates related to lechlemer, Napo's second generation anti-secretory drug product candidate for the symptomatic relief of diarrhea in cholera patients, Jaguar's recently launched Entheogen Therapeutics Initiative which focuses on psychoactive and psychedelic product candidates for mood disorders and mental health indications from the Company's library of 2,300 plants, and Jaguar's Canalevia ™ animal health drug product candidate. As announced, Napo is receiving preclinical services support from the National Institute of Allergy and Infectious Diseases for a key preclinical study initiated January 6, 2021 for lechlemer for the proposed cholera-related indication. Jaguar is pursuing conditional approval in the U.S. for Canalevia for the treatment of chemotherapy-induced diarrhea in dogs and exercise-induced diarrhea in dogs.

Participation Instructions for Investor Webcast

When: Thursday, January 14 at 11:30 a.m. Eastern Time

Participant Registration & Access Link: **Click Here**

The terms "long-hauler" and "chronic COVID" refer to COVID-19 survivors who suffer with symptoms which may include gastrointestinal distress (i.e., diarrhea, constipation, nausea, pain), fatigue, brain fog, forgetfulness, cardiovascular effects, and arthritis, for an extended period after recovery. It is theorized that these symptoms may result when the immune system in COVID-19 survivors continues to overreact even though the infection has passed.

Endpoints being explored in Europe for possible clinical trials of crofelemer for the proposed COVID-related indication include prophylaxis and/or symptomatic relief of diarrhea, reduction in inflammatory gut markers, gut biome restoration, and reduction in viral fecal shedding.

Napo has conducted intellectual property filings in support of the development of crofelemer for the potential indication of addressing inflammatory diarrhea, including specifically in a long-hauler post-COVID recovery situation. As with all potential follow-on indications, Napo prioritizes IP protection. Napo currently holds approximately 144 patents, the majority of which do not expire until 2027 - 2031, and approximately 39 patents pending.

Mytesi (crofelemer delayed release tablets), the only oral plant-based prescription medicine approved under U.S. Food and Drug Administration (FDA) Botanical Guidance, is a novel, first-in-class anti-secretory agent which has a basic normalizing effect locally on the gut, and this mechanism of action has the potential to benefit multiple disorders. Mytesi is a non-opiate chloride ion channel modulating antidiarrheal medicine that is approved in the U.S. by the FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

About Jaguar Health, Inc. and Napo Pharmaceuticals, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, specifically chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

For more information about Jaguar, please visit https://jaguar.health. For more information about Napo, visit www.napopharma.com.

About Mytesi®

Mytesi® (crofelemer delayed release tablets) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi® is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi®. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

More information and complete Prescribing Information are available at Mytesi.com. Crofelemer, the active ingredient in Mytesi®, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's plans to explore the possibility of obtaining conditional marketing authorization in Europe to support development and commercialization of crofelemer for the proposed indication of prophylaxis and/or symptomatic relief of inflammatory diarrhea, the Company plans to request meetings with the EMA, Swissmedic, and the MHRA, the Company's belief that, with the appearance of more transmissible mutated strains of COVID-19, the potential population of post-COVID-19 recovery patients suffering from gastrointestinal distress associated with long-hauler syndrome may expand significantly, the expectation that the long-hauler population experiencing gastrointestinal distress could potentially range between 20 to 70 million people in Europe, the Company's belief that its plans to pursue conditional marketing authorization in Europe for the COVID-related indication may add additional value to the potential COVID-related indication, the Company's expectation that it will select its desired financing pathway for the COVID-related indication no later than the end of this quarter, the belief that the Mytesi (crofelemer) mechanism of action has the potential to benefit multiple disorders, and the Company's plan to host an investor webcast on January 14, 2021. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this release are only predictions. Jaguar has based these forward-looking statements largely on its current expectations and projections about future events. These forward-looking statements speak only as of the date of this release and are subject to a number of risks, uncertainties and assumptions, some of

which cannot be predicted or quantified and some of which are beyond Jaguar's control. Except as required by applicable law, Jaguar does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

[1]"Dr. Fauci Warns These COVID Symptoms Can Last for Months", Alex Korab, Newsbreak. https://www.newsbreak.com/news/2104072336660/dr-fauci-warns-these-covid-symptoms-can-last-for-months.

[2]"Doctors Begin to Crack Covid's Mysterious Long-Term Effects", Sarah Toy, Sumathi Reddy, Daniela Hernandez, Wall Street Journal, November 1, 2020. https://www.msn.com/en-us/health/health-news/doctors-begin-to-crack-covid-s-mysterious-long-term-effects/ar-BB1aAS6V.

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accesswire.com
https://www.accesswire.com/623751/Jaguar-Health-Exploring-Possibility-of-Conditional-Marketing-Authorization-for-Proposed-Inflammatory-Diarrhea-Indication-for-Crofelemer-Initially-in-Long-Hauler-COVID-19-Recovery-Patients-in-Europe